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ATTORNEY DOCKET NO. FIRST NAMED INVENTOR APPLICATION NO. **FILING DATE** 19603/606-(C D SODERLUND 09/428,371 10/28/99 **EXAMINER** HM12/0313 ZARA, J MICHAEL L GOLDMAN **ART UNIT** PAPER NUMBER NIXON PEABODY LLP CLINTON SQUARE PO BOX 1051 1635 ROCHESTER NY 14603 **DATE MAILED:** 03/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

Application No. 09/428,371 Office Action Summary

Applicant(s)

Soderlund et al

Examiner

Zara, Jane

Group Art Unit 1635

Responsive to communication(s) filed on	
Responsive to communication(s) filed on	··
Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.	
A shortened statutory period for response to this action is set to expire is longer, from the mailing date of this communication. Failure to respirapplication to become abandoned. (35 U.S.C. § 133). Extensions of 37 CFR 1.136(a).	ond within the period for response will cause the
Disposition of Claims	
X Claim(s) 41-52 and 78-83	is/are pending in the application.
Of the above, claim(s)	is/are withdrawn from consideration.
Claim(s)	
	is/are rejected.
Claim(s)	
☐ Claims	
Application Papers  See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  The drawing(s) filed on is/are objected to by the Examiner.  The proposed drawing correction, filed on is approved disapproved.  The specification is objected to by the Examiner.  The oath or declaration is objected to by the Examiner.  Priority under 35 U.S.C. § 119  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  All Some * None of the CERTIFIED copies of the priority documents have been received.  received in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau (PCT Rule 17.2(a)).  *Certified copies not received:	
<ul> <li>□ Acknowledgement is made of a claim for domestic priority under</li> <li>Attachment(s)</li> <li>□ Notice of References Cited, PTO-892</li> <li>☒ Information Disclosure Statement(s), PTO-1449, Paper No(s).</li> <li>□ Interview Summary, PTO-413</li> <li>□ Notice of Draftsperson's Patent Drawing Review, PTO-948</li> <li>□ Notice of Informal Patent Application, PTO-152</li> </ul>	
SEE OFFICE ACTION ON THE FOLLOWING PAGES	

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#### **DETAILED ACTION**

#### **Priority**

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). The updated status of Application Serial No. 08/772,512, now US Patent No. 6,022,705, has to be included in the specification.

### Specification

The SEQ ID Nos are used incorrectly in various parts of the specification. On page 23, SEQ ID NO: 3 is referred to as a nucleotide sequence rather than as an amino acid sequence (i.e. lines 21-24). These inconsistencies must be corrected by the Applicants.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-52 and 78-83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

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in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to methods of screening a chemical agent for its ability to modify sodium channel function comprising expression of a voltage-sensitive sodium channel (VSSC) in a host cell, or additionally coexpressing tip E protein in a host cell, exposing the cell to a chemical agent and determining whether the chemical agent modifies the function of the VSSC by monitoring either sodium or guanidinium transport through said VSSC, wherein said VSSC has been determined to confer either susceptibility or resistance to an insecticide in *Musca domestica*.

The specification as filed fails to provide any particular guidance for the translation, characterization of translated protein(s), transfection or functional expression of gene products of SEQ ID Nos: 1 and 2 in suitable host cells. The specification as filed teaches only the isolation and determination of nucleic acid sequences of SEQ ID Nos: 1 and 2 and the determination of putative amino acid sequences which are encoded by these genes. One skilled in the art would not accept on its face the purported amino acid sequence determinations derived from nucleic acid sequences as being representative or correlative of translated functional protein products in vitro or in a host cell and further with methods of assaying chemical agents which modify protein function in view of the lack of guidance in the specification and known unpredictability associated with the functional expression of a gene of known sequence and the determination of assay parameters for normal and altered functions of an expressed protein or proteins in a host

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cell. The specification as filed fails to provide any particular guidance which resolves the known unpredictability in the art associated with the functional expression of a nucleotide sequence and the determination of parameters to be used in assaying for altered function of a purported protein and specifically regarding the instant nucleotide sequences (SEQ ID NOS: 1 and 2) encoding purported VSSC's conferring either susceptibility or resistance to an insecticide in *Musca domestica*.

The quantity of experimentation required to practice the invention as claimed would require the de novo expression of the purported VSSC's which are encoded by SEQ ID Nos: 1 and 2 in *Xenopus* oocytes, *Drosophila Schneider* cells, *Drosophila Kc* cells, *SF9* cells and *High Five* cells. The de novo determination of parameters which define normal function of said purported VSSC's in a host cell, as well as examples of positive and negative controls for chemical agents which modify VSSC function in said host cell are also required to practice the invention as claimed. Since the specification fails to provide any particular guidance in this regard, and since determination of these factors for a particular nucleic acid sequence is highly unpredictable, it would require undue experimentation to practice the invention claimed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (703)-306-5820. The examiner's supervisory primary examiner is George Elliott who can be contacted at (703)-308-4003.

George C. Elliott, Ph.D. Supervisory Patent Examiner Technology Center 1600